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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,755	10/30/2001	Toshihiro Shimizu	2522 US2P	1478
23115	7590	11/23/2005	EXAMINER	
TAKEDA PHARMACEUTICALS NORTH AMERICA, INC INTELLECTUAL PROPERTY DEPARTMENT 475 HALF DAY ROAD SUITE 500 LINCOLNSHIRE, IL 60069			TRAN, SUSAN T	
			ART UNIT	PAPER NUMBER
			1615	
DATE MAILED: 11/23/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/017,755

Applicant(s)

SHIMIZU ET AL

Examiner

Susan T. Tran

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5,7,9,11-19,21-24,29,31,50 and 51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,7,9,11-19,21-24,29,31,50 and 51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Receipt is acknowledged of Request for Extension of Time, and Amendment filed 09/06/05.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5, 7, 9, 11-19, 21-24, 29, 31, 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundberg (US 6,132,770).

Lundberg teaches an effervescent tablet comprising mixture of enteric-coated pellets (beads, particles, granules) containing proton pump inhibitor (ppi) core (acid-labile active substance) (column 3, lines 59 through column 4, lines 1-19). The core material is chosen from celluloses, sugar, non-pareils, or mixture thereof, having size of 0.1-4 mm (100-4000  $\mu$ m) (column 8, lines 11-54). The ppi is mixed with filler, binder, lubricant, disintegrant, surfactant, other additives, and alkaline reacting agent (basic salt), including, calcium and magnesium salts (column 8, lines 55 through column 9, lines 1-5). The filler, binder, lubricant, disintegrant, surfactant, and other additives, including sodium lauryl sulfate, microcrystalline cellulose, mannitol, and hydroxypropyl cellulose are disclosed in column 22, lines 53-57). The pellets are coated with one or

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more enteric coating layers comprising methacrylic acid copolymers, and an over coating layer (column 10, lines 16 through column 11, lines 1-21). The coated pellets are then compressed to tablets having hardness of 51-100 N (which if converted into kg would fall within the claimed range), and disintegrating time is about 55 seconds (see examples).

Lundberg does not teach the content of hydroxypropoxyl group in the hydroxypropyl cellulose as claimed in claims 52 and 53. However, Lundberg teaches the use of hydroxypropyl cellulose within the claimed amount (examples 5, 6, 8, and 12) to obtain the same result, namely, an effervescent (disintegrable) tablet having the claimed hardness and disintegrating time. Accordingly, it would have been obvious to one of ordinary skill in the art to, by routine experimentation determine a suitable hydroxypropoxyl group of the hydroxypropyl cellulose to obtain the claimed invention, because the reference teaches the use of a similar compound to achieve the claimed tablet having the desired hardness and disintegration time.

It is noted that Lundberg does not expressly teach the claimed amounts of the ingredients of claims 14-16. However, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

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Claims 1-3, 5, 7, 9, 11-19, 21-24, 29, 31, 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundberg (US 6,132,770), in view of Watanabe et al. (Biol. Pharm. Bull. Vol. 18, No. 9).

Lundberg is relied upon for the reason stated above. Lundberg does not explicitly teach the oral disintegration time in one minute or less.

Watanabe teaches a rapid disintegrate compressed tablet comprising crystalline cellulose and low-substituted hydroxypropyl cellulose (L-HPC) (see page 1308, materials and methods section). The tablet which is rapidly disintegrated and dissolved in the mouth within 30 second, and having a crushing strength of 8-18 kgf (see page 1308, and page 1309, results and discussion section). Thus, it would have been obvious for one of ordinary skill in the art to prepare the effervescent tablet of Lundberg using crystalline cellulose and L-HPC in view of the teaching of Watanabe to obtain the claimed invention, because the references teach the advantageous results in the use of similar disintegrating agents for the same purpose, such as, Lundberg teaches the effervescent tablet is especially suitable for patients with swallowing disorders and in pediatrics (column 3, lines 53-55), and Watanabe teaches that it is necessary to develop a new type of tablet having the characteristics of rapid disintegration and dissolution in saliva suitable for elderly patients, and patients having difficulties or experience inconvenience in swallowing (see page 1308).

***Response to Arguments***

Applicant's arguments filed 09/06/05 have been fully considered but they are not persuasive.

Applicant requests for further clarification of the 102(e) rejection by Lundberg US 6,132,770. In response to applicant's argument, the 102(e) rejection by Lundberg has been withdrawn in view of applicant's Amendment filed 12/14/04, incorporating the subject matter of claim 25 into claim 1.

Applicant argues that the Examiner is still mistaken in thinking that since the cited reference teaches that an effervescent tablet has a disintegrating time of about 55 seconds, that the aspects of the invention presently claimed are obvious. In response to applicant's arguments, the Examiner fully understand applicants' remarks, however, upon reconsideration, the instant claims are obvious for the following reasons:

1) Although Lundberg does not expressly show the oral dissolution time, applicant has not present data showing that the tablet taught by Lundberg does not have the claimed oral disintegration time, because Lundberg does teach that the tablet having a disintegrating time of about 55 seconds in water (see examples). The Shimizu Declaration dated 10/14/04 does not, at all, show the disintegrating time in the mouth of the tablet taught by Lundberg. The Declaration only states the uncomfortable of large amount of carbon dioxide evolved if an effervescent tablet of Lundberg is taken orally without water. However, the result of discomfort is not a property that would aid in distinguishing over the teachings of Lundberg.

2) Although Lundberg does not expressly teach disintegrating the tablet in the mouth, however, nothing in Lundberg prevents or prohibits a patient to put the effervescent tablet taught in the mouth. Moreover, nothing in Lundberg would prevent a patient to put or chew the tablet and then using water or juice after chewing, or after the tablet has disintegrated in the mouth.

Applicants' reasons for not showing a side-by-side comparison have been fully consider but are not persuasive in view of the following reasons:

1) Inoperable due to engine failure is not a relevant analogy, because the Declaration does not show or declare that the effervescent taught by Lundberg is inoperable for oral administration. The Declaration only shows that large amount of CO<sub>2</sub> evolved would result in discomfort or uncomfortable (see page 4, second paragraph). However, nowhere in the Declaration states that the effervescent tablet of Lundberg is inoperable for oral administration.

2) The Declaration confirms that the effervescent tablet of Lundberg does disintegrate in the mouth.

3) It is noted that the Declaration requires the tablet to be held in the mouth for 1 minute. However, the dissolution time recites in the claims is from about 5 seconds to about 55 seconds. First, the Declaration does not show that the tablet of Lundberg does not disintegrate in the mouth within the claimed time. Second, the Declaration does not show that the tablet of Lundberg would result in discomfort if held in a mouth for a period of less than 1 minute.

4) Finally, as discussed above, nothing in Lundberg would prevent or prohibit one to chew or dissolve the tablet of Lundberg in the mouth, and then drink water or juice if there is any discomfort. It is noted that the claimed invention does not preclude the use of water in concurrent with or after placing the tablet in the mouth.

In response to applicant's argument that Lundberg is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Lundberg teaches the effervescent tablet having disintegrating time in about 55 seconds using similar ingredients being claimed to obtain an oral tablet suitable in pharmaceutical art.

Applicant states that so far four Declarations have been submitted in the pending application, to try to show the Examiner the differences between cited art and the presently claimed invention. Despite applicant's every attempt to educate the Examiner, she continues to reject the present claims. However, in four of the Declarations submitted by the applicant, none of which show that the tablet of Lundberg does not disintegrate in the mouth within the claimed time.

Applicant argues that Watanabe is clearly directed to tablets which can be dissolved orally with only saliva, while Lundberg is not directed to such tablets. Therefore, there would be no reason to combine the teachings of references directed to two different methods of tablet administration. In response to applicant's argument, the

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test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, Watanabe teaches it is necessary to develop a new type of tablet that is rapidly disintegrated and dissolved in the mouth useful for use when water is not available. Watanabe further teaches the useful tablet is suitable for elderly patients, and patients having difficulties or experience inconvenience in swallowing (see page 1308). Therefore, it would have been obvious to one of ordinary skill in the art to modify the effervescent tablet of Lundberg to obtain a result similar to that of Watanabe, because Lundberg teaches the same desire that was recognized by Watanabe, namely, tablet that is especially suitable for patients with swallowing disorders and in pediatrics.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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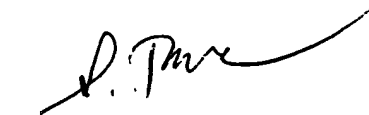
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Patent Examiner  
Art Unit 1615